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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,947	07/25/2000	BRUCE TOWE	A31178PCTA	4172

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,947

Applicant(s)

TOWE, BRUCE

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 and 10-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Guilbeau et al.

Guilbeau et al. teach a systems for the determination of glucose in blood by the reaction of the blood with the enzyme glucose oxidase. The reaction occurs in a hollow membrane and the temperature of the reaction is monitored. Increases in temperature are proportional to the glucose in the sample. Column 5 lines 5-18 teach the thermopile is composed of a plurality of junctions. Column 5 lines 58-62 teach a standard curve created by using known concentration of glucose which has been read on the claimed glucose calibration compound.

Claims 12-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burgess.

In light of the 35 USC 112 second paragraph issues noted above, for the purposes of examination claim 12 will be treated as though it were an independent claim.

Burgess teaches a system for the detection of an analyte using a reagent that reacts with the analyte. Column 3 lines 45-50 teach the reaction may emit visible light (read on the claimed color change). Column 6 lines 65 through column 7 teach the reaction may be a fluorescent emission. Column 4 lines 18-20 teach the use of a sweep fluid.



Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guilbeau et al. alone or in view of Williams.

See Guilbeau et al. supra.

Guilbeau et al. are silent to the claimed polymers used to construct the device.

The court decided In re Leshin (125 USPQ 416) that mere selection of a plastic based upon its suitability of intended use would have been obvious. It would have been within the skill of the art to modify Guilbeau et al. and use polymers, such as acetate, polysulfone, polyacrylonitrile, cellulose and mixtures thereof in view of Leshin.

Williams teaches a similar device for the determination of glucose concentration by the monitoring the temperature with a thermocouple of the subsequent reaction with glucose oxidase. Williams teaches in column 6 lines 41-47 that cellulose is a suitable material of construction because it is selectively permeable to blood constituents of lower molecular weight, such as glucose.

It would have been within the skill of the art to modify Guilbeau et al. in view of Williams and use a known and convention material of construction, such as acetate, to gain the above advantages.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess.

Art Unit: 1743

See Burgess supra.

Burgess is silent to the type of fluid used as the sweep fluid .

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well known results. When choosing a sweep fluid one would choose a fluid that would not react with the analytes of interest. Both water and saline are known, inexpensive and readily available fluids that would not react with the analyte of interest or harm the host upon which the test are performed. It would have been within the skill of the art to modify Burgess and use water or saline as the sweep fluids to gain the above advantages and/or optimization of a result effective variable.

Response to Arguments

Applicant's arguments filed 5/28/02 have been fully considered but they are not persuasive.

Applicants remarks concerning the 35 USC 112 issues were convincing and the 35 USC 112 second paragraph rejections have been vacated.

Applicants state Guilbeau et al. fails to teach a microflow system including a reagent. The Office maintains the art is indistinguishable from the claims and meets every element. With respect to the claimed reagents the office refers to In re Rishoi et al. (94 USPQ 71) who teaches the liquid within the device is not a structural limitation and cannot impart patentability over the prior art not having the claimed liquid.

Applicants state Burgess fails to teach a sensing system capable of being immersed within the test fluid. These remarks are not commensurate in scope with the

Art Unit: 1743

instant claims that are not directed to immersion. Even if the step of immersing the device in the test fluid were made, the Office notes the method of intended use of a device is of no patentable moment.

Applicants state there is no reason or motivation to combine Guilbeau et al. and Williams. The Office maintains Williams teaches the desirability to use cellulose and this is sufficient motivation to make the combination.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for

Art Unit: 1743

the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
Art Unit 1743

September 4, 2002